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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

09/654,223

Applicant(s)

DEDIEU ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on September 8, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-21 and 23-25 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 08/646,246.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/31/00 6) ☒ Other: *examiner's amendment*.

Claim 22 has been canceled; claims 2, 4, 6, 9, 12, 15, and 20 have been amended by the amendment dated September 8, 2003.

Claims 1-21, 23-25 are pending.

A review of the entire reissue application has discovered the following deficiency:

The reissue oath or declaration (filed August 31, 2000) is defective because the declaration does not comply with 37 CFT 1.63 (4), e.g., the phrase "the original first and joint inventors" is not present any where in the declaration. A new oath or declaration is required.

Furthermore, the examiner would like to advise applicant that any newly filed oath or declaration, in addition to complying with 37 CFT 1.63, must comply with 37 CFR 1.175.

§ 1.175 Reissue oath or declaration.

(a) The reissue oath or declaration in addition to complying with the requirements of § 1.63, must also state that:

(1) The applicant believes the original patent to be wholly or partly inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than the patentee had the right to claim in the patent, stating at least one error being relied upon as the basis for reissue; and

(2) All errors being corrected in the reissue application up to the time of filing of the oath or declaration under this paragraph arose without any deceptive intention on the part of the applicant.

(b)

(1) For any error corrected, which is not covered by the oath or declaration submitted under paragraph (a) of this section, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant. Any supplemental oath or declaration required by this paragraph must be submitted before allowance and may be submitted:

(i) With any amendment prior to allowance; or

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(ii) In order to overcome a rejection under 35 U.S.C. 251 made by the examiner where it is indicated that the submission of a supplemental oath or declaration as required by this paragraph will overcome the rejection.

(2) For any error sought to be corrected after allowance, a supplemental oath or declaration must accompany the requested correction stating that the error(s) to be corrected arose without any deceptive intention on the part of the applicant.

(c) Having once stated an error upon which the reissue is based, as set forth in paragraph (a)(1), unless all errors previously stated in the oath or declaration are no longer being corrected, a subsequent oath or declaration under paragraph (b) of this section need not specifically identify any other error or errors being corrected.

(d) The oath or declaration required by paragraph (a) of this section may be submitted under the provisions of § 1.53(f).

[24 FR 10332, Dec. 22, 1959; 29 FR 18503, Dec. 29, 1964; 34 FR 18857, Nov. 26, 1969; para. (a), 47 FR 21752, May 19, 1982, effective July 1, 1982; para. (a), 48 FR 2713, Jan. 20, 1983, effective Feb. 27, 1983; para. (a)(7), 57 FR 2021, Jan. 17, 1992, effective Mar. 16, 1992; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

### **Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a personal interview with Attorney Timothy B. Donaldson on January 15, 2004.

Applicant's response (dated September 8, 2003) has been considered and is found partially persuasive for the withdrawal of the rejections under 35 USC, 112, first paragraph, for claimed embodiments, drawn to a heterologous DNA sequence under the control of an expression signal which is inducible by Epstein-Barr virus (EBV) EBNA

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1, EBNA 2, or by a papilloma virus E6 antigen. As such, the claims have been amended so as to reflect only the patentable claimed subject matter:

Claims 1, 2, 17, 23, and 24 have been amended as indicated below.

1. (Currently Amended) A replication defective recombinant adenovirus comprising a heterologous DNA sequence under the control of an expression signal which is inducible by [the] an Epstein-Barr virus (EBV) antigen, or by a papilloma virus antigen, wherein the EBV antigen is EBNA1 or EBNA2, and wherein the papilloma virus antigen is E6.

2. (Currently Amended) [An] The adenovirus according to claim 1, wherein the expression signal is activated by the EBNA1 antigen, or the EBNA2 antigen.

3. (Currently Amended) [An] The adenovirus according to claim 2, wherein the expression signal consists of a chimeric promoter comprising a sequence which is activated by the EBNA 1 antigen fused upstream of a viral promoter.

17. (Currently Amended) The adenovirus according to claim 2, wherein the expression signal is the EBNA1 responsive element (EBNA1-RE).

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18 (Currently Amended) The adenovirus according to claim 14, wherein the sequence which is activated by the EBNA1 antigen is the EBNA1 responsive element (EBNA1-RE).

23. (Currently Amended) The adenovirus according to claim 20, wherein the promoter sequence is inducible by the EBNA1 antigen.

24. (Currently Amended) The adenovirus according to claim 1, wherein the expression signal is inducible by the papilloma virus E6 antigen.

#### **Issue of surrendering the original ribboned copy of the patent**

The examiner acknowledges that applicant has indicated on the record that applicant would intend to surrender the original patent upon an indication of the allowable subject matter. However, in view of MPEP § 1416, either the original patent, or a statement addressing the loss or inaccessibility of the original patent, must be received before the reissue application can be allowed.

#### **Drawings**

The drawings of record are accepted for printing.

#### **IDS Filed on July 17, 2002**

In the initialed and dated IDS filed on July 17 2002, which was attached to the mailed non-final office action, reference 10 has not been initialed due to the examiner's oversight. Thus, the IDS having reference 10 initialed has been resent to applicant for completeness.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0184**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen  
Primary Examiner  
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DAVE T. NGUYEN  
PRIMARY EXAMINER